REMARKS/ARGUMENTS

The rejections presented in the Office Action dated August 10, 2006 (hereinafter Office Action) have been considered. Claims 1-14 and 35-56 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

The specification has been amended to delete a paragraph on page 4, lines 16-29. This identical paragraph is repeated beginning at page 41, line 27 and is thus redundant in the specification.

Claims 1-4 and 35-36 stand rejected under 35 U.S.C. §101 as being directed toward non-statutory subject matter.

The Examiner asserts that Applicants' invention has no practical application. Applicants respectfully disagree and assert that the rejection is in error because the Examiner's arguments do not provide sufficient evidentiary basis for the rejection. Collection of data and/or evaluation of data by an implantable device has practical application and has utility as described in numerous passages in Applicants' specification and as set forth below.

A rejection under 35 U.S.C. § 101 must a) make a *prima facie* showing that the claimed invention lacks utility and b) provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing. MPEP 2107.01 (II). Furthermore, the *prima facie* showing must be set forth in a well-reasoned statement that articulates sound reasons why a person of ordinary skill in the art would conclude that it is more likely than not that an asserted utility is not credible. Id. The statement should specifically identify the scientific basis of any factual conclusions made in the *prima facie* showing and must explain why any evidence of record that supports the asserted utility would not be persuasive to one of ordinary skill. Id. Furthermore, the Examiner must provide evidentiary support for the *prima facie* case. Id. It is imperative that the Office personnel use specificity in setting forth an initial rejection under 35 U.S.C. § 101 and support any factual conclusions in the *prima facie* showing. Id.

Applicants assert that the rejection is in error because the requisite evidentiary support for a *prima facie* showing that the claimed invention lacks utility has not been provided. The Examiner merely concludes that the collection of data and the evaluation of data are abstractions and are not tangible, without supporting reasons. Applicants assert that the mere conclusory statements do not set forth with specificity the evidentiary basis required for a rejection based on non-utility as required by the MPEP. The Examiner has not established why it is more likely than not that the asserted utilities of the invention are not credible. The Examiner has not specifically identified the scientific basis of factual conclusions or provided evidence that the asserted utility would be unpersuasive to one of ordinary skill in the art. Further, the Examiner has not addressed the utilities described in the specification and provided the Applicants in the previous Office Action response.

Applicants' invention, as recited for example in independent claim 1, is directed to a method for collecting sleep quality data. The method involves detecting physiological and non-physiological conditions related to the sleep quality of a patient. Sleep quality data is collected in part by an implantable device based on the detected conditions. Independent claim 35 recites evaluating the sleep quality data, where the evaluation is performed in part by an implantable device.

Applicants respectfully assert that collecting and/or evaluating sleep quality data, performed in part by an implantable device, has clear, practical, and specific application that would be immediately apparent to one skilled in the art. As discussed in the specification on page 4, beginning at line 11, "an adequate duration and quality of sleep is required to maintain physiological homeostasis. Untreated, sleep disturbances may have a number of adverse health and quality of life consequences ranging from high blood pressure and other cardiovascular disorders to cognitive impairment, headaches, degradation of social and work-related activities and increased risk of automobile and other accidents." Thus one skilled in the art would understand that degradation of sleep quality has many adverse effects.

Furthermore, previous systems for collection and/or evaluation of sleep quality data involve the use of a polysomnographic sleep study at dedicated sleep facility. Such studies

are costly, inconvenient to the patient, and may not accurately represent the patient's typical sleep behavior. (page 10 lines 12-13) Routine monitoring of patient sleep quality may lead to improved diagnosis and treatment. (page 41 lines 20-21) The invention provides less obtrusive sleep quality monitoring and is suited for patients having an implantable device. The invention serves to improve diagnosis of sleep disorders by reducing the inconveniences, unnatural sleep environment issues, and expenses associated with sleep clinic polysomnographic studies. (page 41 lines 22-26) Applicants' respectfully assert that the utility of the novel approaches to collecting and evaluating data related to sleep quality as recited in claims 1-14 and 35-56 would be understood and appreciated by one skilled in the art.

Claims 1-3, 5, 9-14 and 35-46 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,641,542 to *Cho et al.* (hereinafter *"Cho"*).

Applicants disagree with the Examiner's assertion that *Cho* anticipates these claims. However, to expedite allowance of the application, Applicants have amended claims 1 and 35 to indicate that at least one non-physiological condition is a condition other than time. *Cho* does not teach or suggest detecting any non-physiological signal other that time, therefore, Applicant's independent claims 1 and 35, as amended, and any claims depending therefrom, are not anticipated by *Cho*.

Claims 4 stands rejected under 35 U.S.C. §103(a) as being unpatentable over *Cho* in view of U.S. Patent No. 6,361,494 to *Lindenthaler* (hereinafter *"Lindenthaler"*). Claim 6 stands rejected under 35 U.S.C. §103(a) as being unpatentable over *Cho* in view of U.S. Patent No. 5,146,918 to *Kallok et al.* (hereinafter *"Kallok"*). Claims 7 and 8 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Cho* in view of U.S. Patent No. 6,059,725 to *Steinschneider* (hereinafter *"Steinschneider"*).

Each of the obviousness rejections depends on *Cho* in combination with a second reference to teach or suggest all of the limitations of the claims. However, as discussed above with regard to the rejection of claims 1 and 35, *Cho* does not teach or suggest detection of any non-physiological condition other than time. The secondary references used in the rejection of claims 4, 6, 7, and 8 also do not teach or suggest detecting non-

physiological conditions other than time. Thus, the asserted combinations of references do not teach or suggest all of the claim limitations as is required to support a *prima facie* case of obviousness.

Claims 47-56 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Cho* in view of U.S. Patent No. 6,361,494 to *Lindenthaler* (hereinafter *"Lindenthaler"*).

Applicants disagree that claims 47-56 are obvious in view of the combination of *Cho* and *Lindenthaler*. To support a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves itself or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings and there must be a reasonable expectation of success. The teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. MPEP 2143.

The asserted combination does not provide a sufficient basis to support a reasonable expectation of success or the requisite suggestion or motivation to combine or modify the references in the manner suggested by the Examiner. Applicants respectfully maintain their assertion that the Examiner has failed to establish *prima facie* obviousness of Applicants' subject matter recited in claims 47-56.

First, neither *Cho* nor *Lindenthaler* suggest the desirability of the claimed invention. *Cho* describes an implantable approach for detecting and treating specific incidences of sleep apnea, referred to as adverse events (See *Cho*, col. 6 lines 60-65) "Adverse events are measurable events indicating abnormal sleep." The severity of sleep apnea is determined from the adverse events and a decision is made whether to deliver therapy (*Cho*, col. 9 lines 21-23).

The Examiner's argument that it would be obvious to combine *Cho*'s real time detection of specific apnea events with *Lindenthaler*'s method of "prediagnosing" apnea based on pharangeal muscle tone while the patient is awake is unpersuasive. *Cho*'s system involves a real time detection of sleep apnea events so that therapy can be delivered to treat these specific events. *Lindenthaler*'s system does not provide any information about specific sleep apnea events. *Lindenthaler*'s system merely provides a "prediagnosis" of

sleep apnea, which is an indication that a person may experience (or may have experienced) sleep apnea, but cannot detect the occurrence of such an event as required by *Cho*'s system.

The Examiner states that the motivation to combine the references exists because "Lindenthaler teaches the importance of muscle tone in relation to sleep apnea." Applicant respectfully asserts that *Lindenthaler* teaches the importance of muscle tone in the prediagnosis of sleep apnea while the patient is awake. There is no suggestion in either reference as to how this data, collected while the patient is awake, would be useful when combined with the real time apnea detection system of *Cho*. There is no motivation to combine the references in the way suggested by the Examiner.

Further, the proposed combination of *Lindenthaler*'s sensor with the approach taught by *Cho* is unworkable because the combination would render *Cho*'s system unsatisfactory for its intended purpose. The sensor described by *Lindenthaler* can not be used to detect the adverse events in real time described by *Cho*. The use of *Lindenthaler*'s sensor would render *Cho*'s system inoperable to detect the adverse events. *Cho*'s system extracts cycle length and frequency of adverse events and determines whether therapy is required. Without the detection of specific adverse events, the system of *Cho* would not be operable. Thus, one skilled in the art would not be motivated to combine the sensor taught by *Lindenthaler* in the system taught by *Cho*.

For at least these reasons, as well as the reasons set forth in Applicants' previous Office Action response, Applicants respectfully assert that the combination of *Cho* and *Lindenthaler* as proposed by the Examiner do not support a case of *prima facie* obviousness with regard to claims 47-56, and these claims are patentable over the asserted combination.

Claim 50 stands rejected under 35 U.S.C. §103(a) as being unpatentable over *Cho* in view of *Lindenthaler*, as applied above, and further in view of *Kallok*.

Applicant reasserts the arguments made above in connection with the obviousness rejection of claims 47-56 based on *Cho* and *Lindenthaler*. The combination of *Cho*, *Lindenthaler* and *Kallok* also fails to support prima facie obviousness of claim 50 because of the lack of motivation to combine the references, the inoperability of any such

combination, and other reasons. Claim 50 is not obvious in view of the asserted combination of references.

It is to be understood that Applicants do not acquiesce to Examiner's characterization of the asserted art or Applicants' claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to Applicants' claimed subject matter. Moreover, Applicants do not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art, obvious design choices, alternative equivalent arrangements, common knowledge at the time of Applicants' invention, officially noticed facts, and the like. Applicants respectfully submit that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching and suggestion of various features recited in Applicants' pending claims and lack of motivation to combine reference teachings. Applicants, however, reserve the right to address in detail the Examiner's characterizations, conclusions, and rejections in future prosecution.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.058PA) any necessary fees for this filing.

Respectfully submitted,

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